infovac®
KCI Healing by design

User Manual

KCI

WARNING

Important Safety Information Accompanies This Device

Indications, Contraindications, Warnings, Precautions and other Safety Information are contained in the ***V.A.C.® Therapy System Safety Information Sheet***. This information sheet is included with the therapy unit and also included in V.A.C.® Dressing cartons. Please consult the V.A.C.® Therapy System's User Manual and the Safety Information Sheet before applying V.A.C.® Therapy. If there are questions, or if this information sheet is missing, immediately contact your local KCI representative.

Additional product information can be found at www.kci1.com (USA) or www.kci-medical.com (outside the USA).

As with all prescription medical devices, failure to follow product instructions or adjusting settings and performing therapy applications without the express direction and/or supervision of your trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury. For medical questions, please consult a physician. In case of medical emergency, immediately contact your local emergency services provider.

CAUTION: Federal law (US) restricts this device to sale or rental by or on the order of a physician.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

KCI HEREBY DISCLAIMS ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON THE KCI PRODUCT(S) DESCRIBED IN THIS PUBLICATION. ANY WRITTEN WARRANTY OFFERED BY KCI SHALL BE EXPRESSLY SET FORTH IN THIS PUBLICATION OR INCLUDED WITH THE PRODUCT. UNDER NO CIRCUMSTANCES SHALL KCI BE LIABLE FOR ANY INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES AND EXPENSES, INCLUDING DAMAGES OR INJURY TO PERSON OR PROPERTY, DUE IN WHOLE OR IN PART TO THE USE OF THE PRODUCT OTHER THAN THOSE FOR WHICH DISCLAIMER OF WARRANTY OR LIMITATION OF LIABILITY IS EXPRESSLY PROHIBITED BY SPECIFIC, APPLICABLE LAW. NO PERSON HAS THE AUTHORITY TO BIND KCI TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH IN THIS PARAGRAPH.

Descriptions or specifications in KCI printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties except as set forth in the written limited warranty included with this product. Information in this publication may be subject to change at any time. Contact KCI for updates.

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Important Information For Users

In order for KCI products to perform properly, KCI recommends the following conditions. Failure to comply with these conditions will void any applicable warranties.

- Use this product only in accordance with this manual and applicable product labeling.
- Assembly, operations, extensions, re-adjustments, modifications, technical maintenance or repairs must be performed by qualified personnel authorized by KCI.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards.
- Do not operate this product if it has a damaged power cord, power supply or plug. If these components are worn or damaged, contact KCI.
- Do not drop or insert any object into any opening or tubing of this product.
- Do not connect this product or its components to devices not recommended by KCI.
- Use only V.A.C.® Dressings with this product.
- Keep this product away from heated surfaces.
- Although this product conforms to the intent of the standard IEC 60601-1-2 in relation to Electromagnetic Compatibility, electrical equipment may produce interference. If interference is suspected, separate the equipment and contact KCI.
- Avoid spilling fluids on any part of this product.

Fluids remaining on the electronic controls can cause corrosion that may cause the electronic components to fail. Component failures may cause the unit to operate erratically, possibly producing potential hazards to patient and staff. If spills do occur, unplug the unit immediately and clean with an absorbent cloth. Ensure there is no moisture in or near the power connection and power supply components before reconnecting power. If the product does not work properly, contact KCI.

- Do not use this product while bathing/showering or where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into electrical source. Disconnect the unit from dressing and contact KCI.

Notice

This product has been configured from the manufacturer to meet specific voltage requirements. Refer to the Product Information Label for specific voltage.

Introduction

V.A.C.® (Vacuum Assisted Closure®) Therapy is a system that uses controlled continuous or intermittent negative pressure (vacuum) to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by:

- **preparing the wound bed for closure**
- **reducing edema**
- **promoting granulation tissue formation and perfusion**
- **removing exudate and infectious material**

The InfoV.A.C.® Therapy System provides Negative Pressure Wound Therapy (NPWT) and Therapeutic Regulated Acute Care® (SensaT.R.A.C.®) for use on a variety of chronic and acute wound types. This advanced wound healing technology, coupled with microprocessor-controlled therapy units, and first-class technical back-up, can be readily integrated into the clinician's wound healing practice, helping to optimize patient care and manage costs.

Protection Against Hazards

Discard all disposable items (all tubing, connectors, clamps, used canister, used dressings, etc.) in accordance with local medical waste disposal regulations.

Standard Precautions should be used when handling any body fluids or waste. Properly dispose of all parts according to institutional procedures, as well as local, state and federal regulations.

The InfoV.A.C.® Therapy Unit and power supply should be returned to KCI for disposal at the end of their operational life.

Only the power supply provided with the InfoV.A.C.® Therapy Unit (part number M6266106) should be used to power the device or to recharge the battery. Using any other power supply may damage the InfoV.A.C.® Therapy Unit.

The battery in the InfoV.A.C.® Therapy Unit is not a user serviceable part. If battery problems are suspected, the system should be returned to KCI for servicing.

Power cords and tubing may present a tripping hazard. Ensure that all cords and tubing are out of areas where people may walk.

Attaching the InfoV.A.C.® Therapy Unit to Other Devices

The InfoV.A.C.® Therapy Unit may be attached to the footboard of a hospital bed, most wheelchairs or to an IV pole (see pages 6-7). If required, it may be placed on a solid, level surface where it does not cause an obstruction. Ensure unit is placed below the height of the wound and where cables and tubes cannot be caught on passing objects.

The InfoV.A.C.® Therapy Unit is not intended to be carried by ambulatory patients. Consult your physician and contact your local KCI representative for V.A.C.® Therapy units designed for ambulatory patient use.

Devices that can be used with the InfoV.A.C.® Therapy Unit:

- Memory cards
- Infrared devices
- USB devices

InfoV.A.C.® Therapy Unit - Parts Identification

InfoV.A.C.® Power Supply

Before preparing the InfoV.A.C.® Therapy Unit for use, inspect the unit for any damage or contamination. Refer to the *Care and Cleaning* chapter (page 57) of this manual for more information.

The power supply has a two-part cord; one that plugs into a AC wall outlet and one that plugs into the InfoV.A.C.® Therapy Unit. The AC power cord may have different wall plug configurations depending on country requirements.

Use only the power supply provided with the InfoV.A.C.® Therapy Unit (part number M6266106) to power the device or to recharge the battery. Using any other power supply may damage the InfoV.A.C.® Therapy Unit.

Charging the Battery

1. Plug the AC power cord into the power supply.

2. Plug the AC power cord into an AC wall outlet.

3. Locate the white arrow on the InfoV.A.C.® power supply charging cord connector.

4. Plug the InfoV.A.C.® power supply charging cord connector into the power connection on the back of the InfoV.A.C.® Therapy Unit with the white arrow facing up.

It should take approximately four hours to fully recharge the battery. The system can be used while the battery is recharging.

To maximize battery life, keep the unit plugged in.

Battery Charging Indicator Light

When the InfoV.A.C.® power supply is correctly plugged into the InfoV.A.C.® Therapy Unit, the battery charging indicator light on the back of the unit will glow amber as the battery is charging. When the battery is fully charged the battery charging indicator light will glow green.

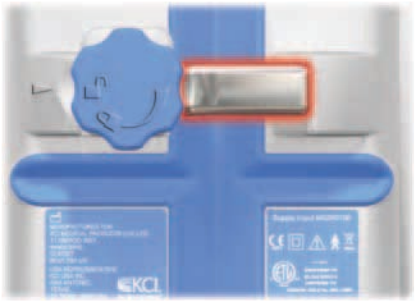
The battery level is shown on the bottom of the touch screen user interface:

Fully Charged

In Use

Battery Low, charge battery soon

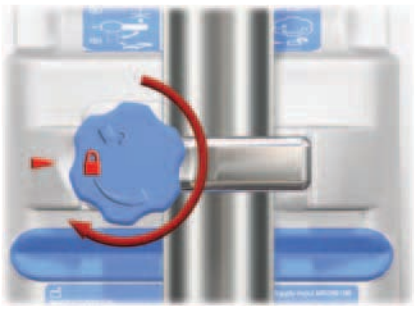
Attaching the InfoV.A.C.® Therapy Unit to an IV Pole



1. Ensure the hanger arm is in the horizontal position.

2. Hold the InfoV.A.C.® Therapy Unit by the carry handle, grip the hanger knob and pull the hanger arm out.

3. Place the hanger around the IV pole ensuring that the pole is in the vertical rubber groove on the rear of the InfoV.A.C.® Therapy Unit. Allow the hanger to close pulling the therapy unit onto the pole.



4. Turn the hanger knob to lock the hanger arm in place. The lock symbol on the hanger knob will align with the arrow on the therapy unit when the mechanism is locked. An audible click also indicates that the mechanism is locked.

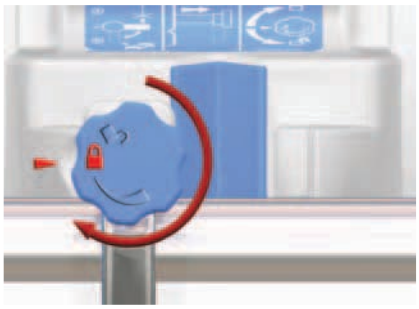
The hanger knob can be turned past the lock position to further secure the InfoV.A.C.® Therapy Unit. Hand tighten only; excessive force or tools should not be used.

Attaching the InfoV.A.C.® Therapy Unit to a Bed Footboard

1. Ensure the hanger arm is in the vertical position.

2. Hold the InfoV.A.C.® Therapy Unit by the carry handle, grip the hanger knob and pull the hanger arm out.

3. Place the hanger over the footboard. Allow the hanger to close pulling the therapy unit onto the footboard.



4. Turn the hanger knob to lock the hanger arm in place. The lock symbol on the hanger knob will align with the arrow on the therapy unit when the mechanism is locked. An audible click also indicates that the mechanism is locked.

The hanger knob can be turned past the lock position to further secure the InfoV.A.C.® Therapy Unit. Hand tighten only; excessive force or tools should not be used.

Releasing the InfoV.A.C.® Therapy Unit from an IV Pole or Bed

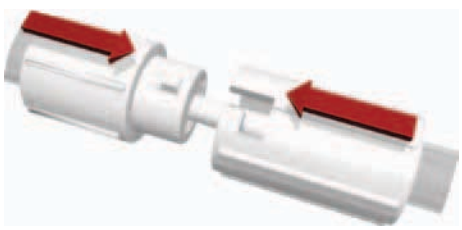
1. Hold the InfoV.A.C.® Therapy Unit by the carry handle.
2. Reverse the attaching procedure.

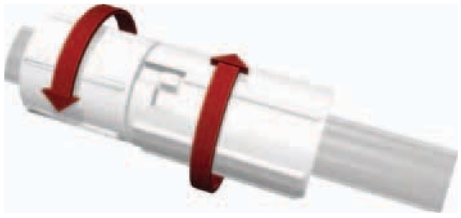
Installing the 500mL and 1000mL Canisters

1. Press Power On/Off to turn the InfoV.A.C.® Therapy Unit on.

2. Attach the canister:
   - Slide the canister into the end of the InfoV.A.C.® Therapy Unit as shown below.
   - Push the canister firmly into place. An audible click signals the canister is correctly installed.

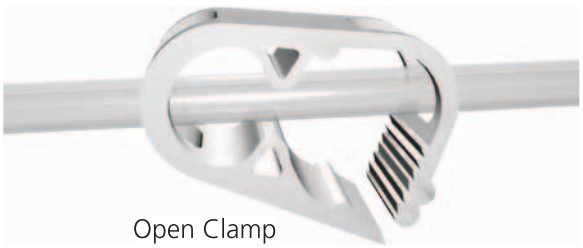
3. Connect the canister tubing to the dressing tubing:
   - Push the connectors together and twist until the locking tabs are fully engaged.





4. Open all tubing clamps as shown below.

Closed Clamp



Open Clamp

Changing the 500mL and 1000mL Canisters

A canister may be changed under routine conditions or under alarm conditions.

Under routine conditions the Canister Release button will NOT be flashing. When changing the canister under routine conditions do NOT turn power off to the InfoV.A.C.® Therapy Unit.

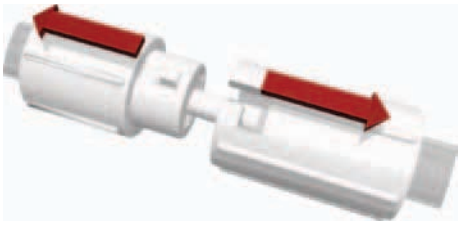
Under alarm conditions the Canister Release button will be flashing. An alarm screen will be displayed and therapy will be off.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

1. Stop therapy by pressing the Therapy On/Off button on the touch screen user interface.

2. Close all tubing clamps as illustrated.

3. Disconnect the canister tubing from the dressing tubing:
   - Twist connectors until the locking tabs are fully disengaged and pull the connectors apart.



4. Press the Canister Release button. The canister will eject but remain in the cradle.

5. Lift the canister out of the cradle.

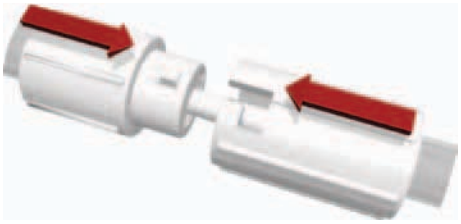
6. Dispose of the canister according to hospital or facility protocol.

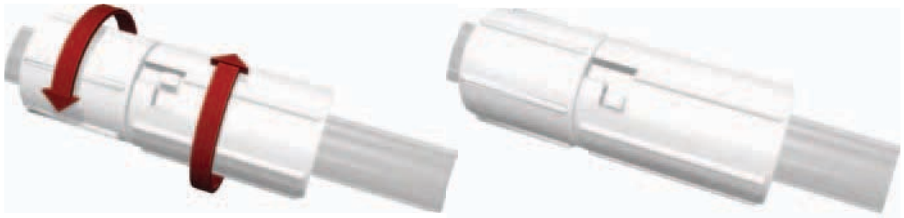
WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Installing the 300mL ActiV.A.C.® Canister

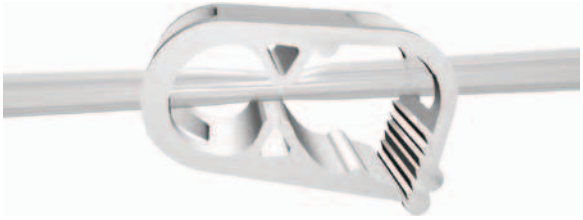
1. Attach the canister:
   - Push the canister firmly into place on the InfoV.A.C.® Therapy Unit as illustrated below.

2. Connect the canister tubing to the dressing tubing:
   - Push the connectors together and twist until the locking tabs are fully engaged.





3. Open all tubing clamps as illustrated.



Closed Clamp

Open Clamp

Removing the 300mL ActiV.A.C.® Canister

When the Canister Release button is pressed, the 300mL canister is NOT held in place by the cradle of the InfoV.A.C.® Therapy Unit. When removing the 300mL canister from the InfoV.A.C.® Therapy Unit ensure that the canister is held FIRMLY before pressing the Canister Release button.

1. Hold the canister firmly.

2. Press the Canister Release button.

Before powering the therapy unit on, ensure that:

- The V.A.C.® Dressing is applied as described in the ***Application Instructions*** supplied with the V.A.C.® Dressing.
- The InfoV.A.C.® Canister is attached as described in the ***Installing the Canisters*** sections of this manual (pages 8 and 11).
- The InfoV.A.C.® Therapy Unit is fitted to a IV pole or footboard or placed as described in the ***Preparation for Use*** chapter of this manual (page 4).

Powering the InfoV.A.C.® Therapy Unit On/Off

Power On:

1. Connect the InfoV.A.C.® Therapy Unit to the power supply as described in the ***Preparation for Use*** chapter of this manual (page 4).

2. Press and hold the Power On/Off button for approximately two seconds to turn the InfoV.A.C.® Therapy Unit on. The Power On/Off button will illuminate and the touch screen user interface will activate.

The InfoV.A.C.® Therapy Unit start up process will briefly be displayed followed by a Warning Screen.

Power Off:

Press and hold the Power On/Off button for approximately two seconds to turn the InfoV.A.C.® Therapy Unit off.

The Power On/Off button will flash for ten seconds after which the InfoV.A.C.® Therapy Unit will automatically shut down.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Operating the Touch Screen User Interface

The *touch sensitive* screen on the front of the unit displays information on current system operations and settings, and provides an interface for changing settings and operation.

The operation of the touch screen user interface is detailed in the following pages.

The touch screen user interface should ONLY be operated by finger or the supplied stylus (see page 3). Using pens or pointing devices will damage the screen and may affect the proper function of the unit.

Control Screens

The three levels of Control Screens are Patient Mode, Clinician Mode and Restricted Mode.

Patient Mode

The clinician may select Patient Mode to allow a patient to control certain elements of their therapy. This mode does not allow the patient to access or alter therapy settings.

The patient can activate Night Mode and the Screen Guard, access the Help screens, and respond to alarms.

Clinician Mode

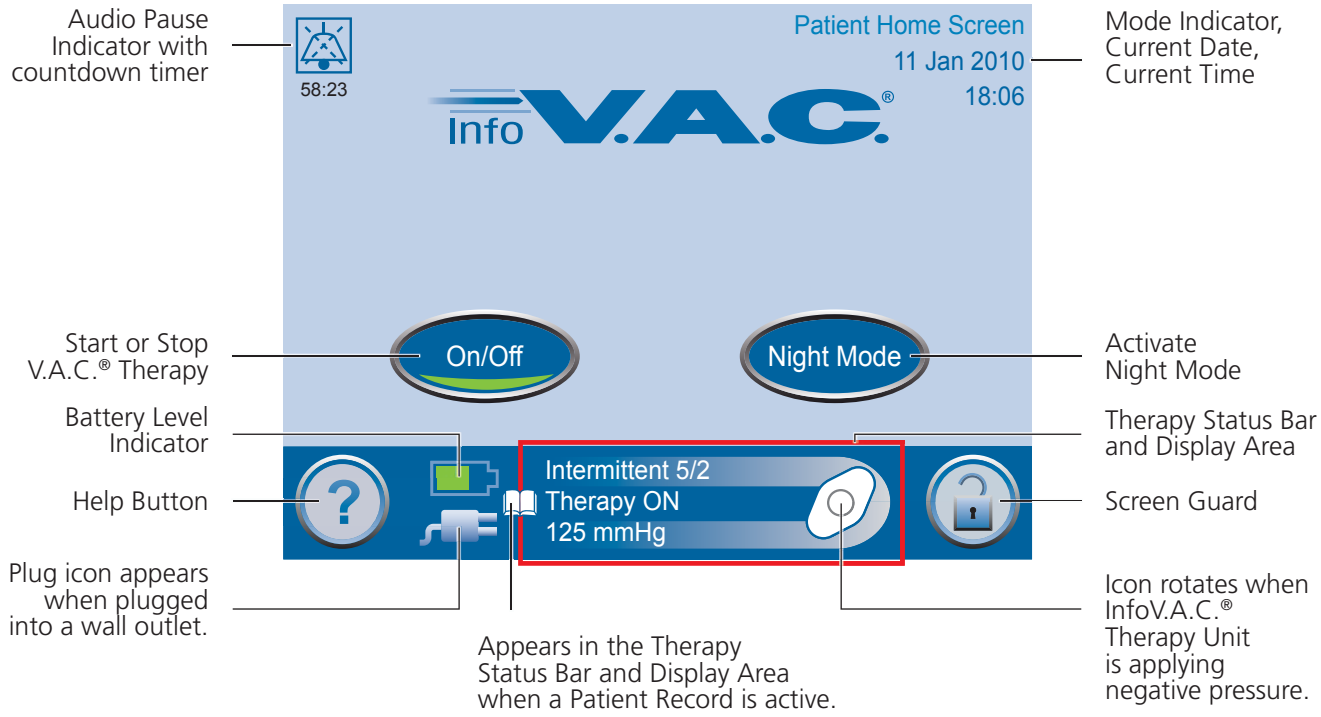
The Clinician Mode screens allow a clinician to set and change therapy settings, view therapy history and access the Restricted Mode (see below).

Restricted Mode (Patient History)

The Restricted Mode screens allow access to patient wound images, image area trend charts and other patient health information that the caregiver has entered. From this mode the clinician can adjust the Leak Alarm sensitivity, and export therapy and patient histories. A secure password system protects the Restricted Mode from unauthorized access.

The secure password is created by the healthcare professional, not KCI. If a new password is created, all patient history associated with the previous password is deleted. All information is automatically deleted when therapy unit is returned to KCI.

Patient Mode Control Screens


Audio Pause Indicator with countdown timer
58:23
Patient Home Screen
11 Jan 2010
18:06
Mode Indicator, Current Date, Current Time
Start or Stop V.A.C.® Therapy
On/Off
Night Mode
Activate Night Mode
Battery Level Indicator
Therapy Status Bar and Display Area
Help Button
Intermittent 5/2
Therapy ON
125 mmHg
Screen Guard
Plug icon appears when plugged into a wall outlet.
Icon rotates when InfoV.A.C.® Therapy Unit is applying negative pressure.
Appears in the Therapy Status Bar and Display Area when a Patient Record is active.

A lighted green crescent means the function is on.

An unlit crescent means the function is off.

Common Screen Control Buttons

Press to access *Help Menu*.

Press to activate Screen Guard feature to help prevent unintentional screen changes. This feature should be used when cleaning the touch screen user interface. To release the Screen Guard, press 1 and then 2, which will appear on the screen when Screen Guard is active.

Navigation Buttons

Press to leave the current screen.

Press to stop action in progress.

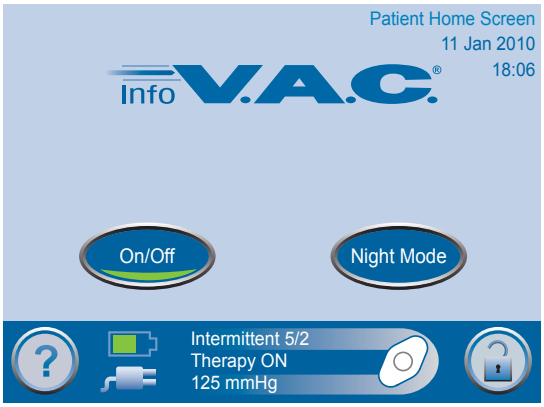
Press to go to the next screen.

Press to return to the previous screen.

Press to acknowledge the action is complete and display the next screen.

Press to scroll through available selections. Press and hold to scroll rapidly.

Night Mode Function

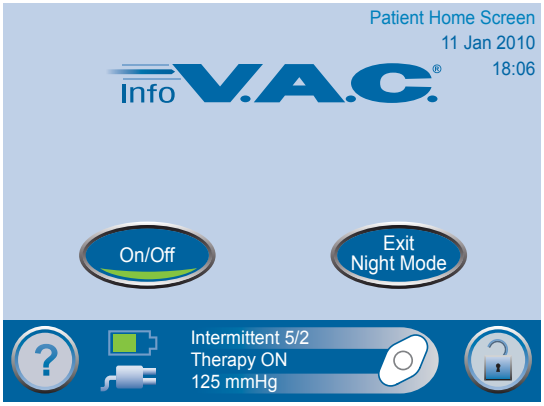


The Night Mode function on the *Patient Home Screen* can be used to dim disrupting lights from the therapy unit during nighttime therapy use.

Press to activate the Night Mode function from the *Patient Home Screen*. A confirmation screen will be displayed before Night Mode is immediately activated.

When the Night Mode function is active, therapy continues as normal. The touch screen user interface will darken and the green Power On/Off button will dim.

The Night Mode function will deactivate in the event of an alarm.

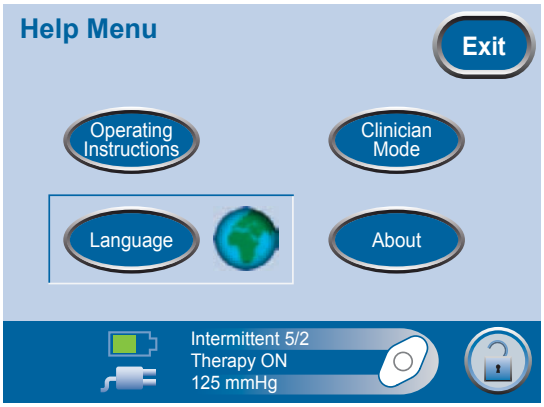


During Night Mode, the screen will illuminate when touched and display the *Patient Home Screen*.

Should the touch screen user interface be touched while night mode is active, the screen will automatically darken after two minutes of inactivity.

Press to deactivate the Night Mode function.

Patient Mode Help Menu Screen



Press to access the Patient Mode *Help Menu* screen from any Patient Mode screen where this button appears.

Press to access Operating Instructions.

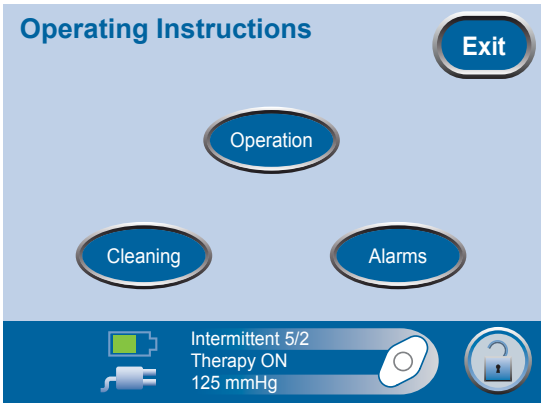
Press to access the *About* screen for information regarding the InfoV.A.C.® Therapy Unit software.

Press to access Clinician Mode (press and hold for three seconds).

Press to access the *Language* screen to select the appropriate language.

Press to return to the *Patient Home Screen*.

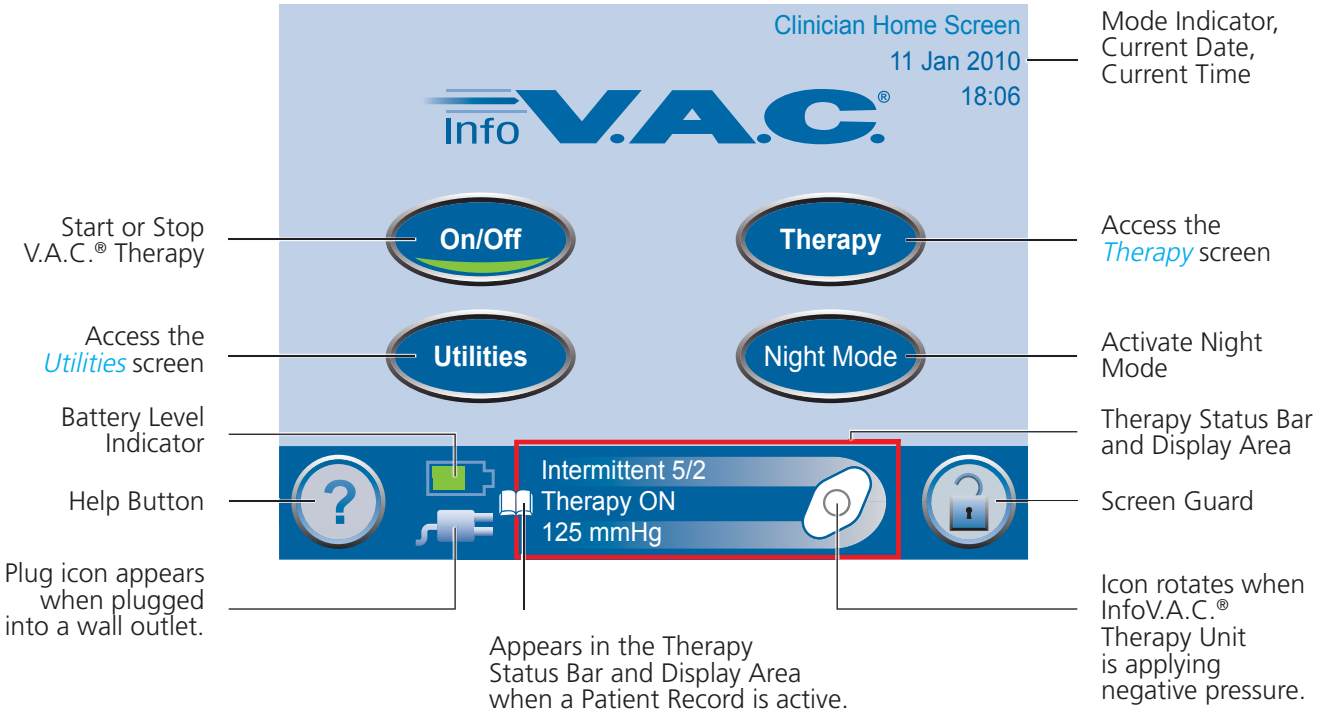
Operating Instructions Screen



The Operating Instructions provide help in operating the InfoV.A.C.® Therapy Unit.

Press to access the *Operating Instructions* screen from the *Help Menu* screen to view basic instructions for operation, cleaning and alarms.

Clinician Mode Control Screens



A lighted green crescent means the function is on.

An unlit crescent means the function is off.

Common Screen Control Buttons

Press to access Clinician Mode *Help Menu*.

Press to activate Screen Guard feature to help prevent unintentional screen changes. This feature should be used when cleaning the touch screen user interface. To release the Screen Guard, press 1 and then 2, which will appear on the screen when Screen Guard is active.

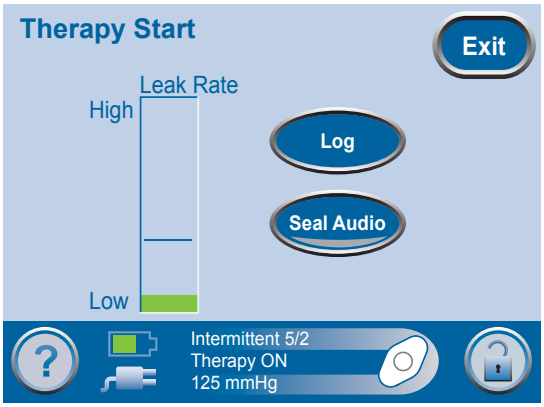
To Return to the Patient Home Screen

Press the Help button.

Press Patient Mode on the *Help Menu* screen.

Press and hold OK until the *Patient Home Screen* returns.

Therapy Start Screen



From the *Clinician Home Screen* press Therapy On/Off to access the *Therapy Start* screen.

A green bar graph indicates that the InfoV.A.C.® Therapy System is operating normally.

Ensure that a new V.A.C.® Dressing has been applied and therapy settings have been selected per physician's orders before starting therapy.

From this screen the clinician can use the Seal Check™ tool to view the integrity of the V.A.C.® Dressing, or use the Log tool to record a canister change or record the number of foam pieces used during a dressing change.

Seal Check™ Overview

Seal Check™ is used to help find negative pressure leaks.

Seal Check™ features:

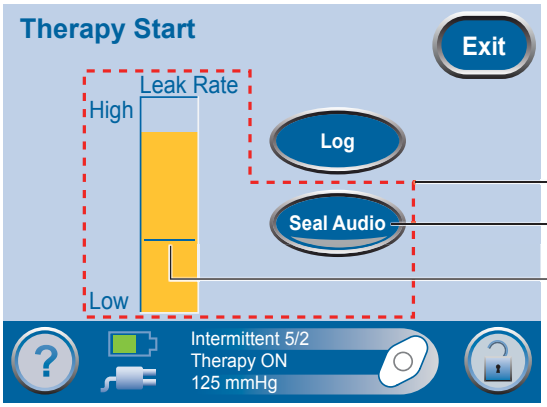
- an audible tone that changes frequency as the rate of the leak changes. Pressing the Seal Audio button will switch between the audible tone being on or off.
- a real time bar graph that gives a visual indication of the rate of the leak.

Access the Seal Check™ tool three different ways:

- When Therapy is started from the *Clinician Home Screen*, discussed on the following pages.
- When the Seal Check™ button is pressed on the *Therapy* screen.
- When the Seal Check™ button is pressed on the *Leak Alarm* screen after the InfoV.A.C.® Therapy Unit detects a possible leak.

Patients only have access to the Seal Check™ tool through the *Leak Alarm* screen when the InfoV.A.C.® Therapy Unit detects a possible leak.

How to Use Seal Check™ (When Starting Therapy)



From the *Clinician Home Screen* press Therapy On/Off to access the *Therapy Start* screen.

Seal Check™ tool

Turn the Seal Audio tone On or Off

Line on bar graph is the transition point from green to orange and vice-versa.

An orange bar graph indicates a significant leak.

The Seal Check™ feature provides an audible tone and bar graph to assist in finding leaks. The frequency of the audible tone and the height of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph decreases in height as the leak is found and corrected.

During initial dressing draw down, the bar graph should turn orange and then return to green if there are no significant leaks.

Most leaks occur in three specific areas.

- where the V.A.C.® Drape meets the skin.
- where the SensaT.R.A.C.™ Pad is attached to the V.A.C.® Drape.
- at tubing connections.

Finding a Leak Using Seal Check™

1. Ensure connector between dressing tubing and canister tubing is properly locked.

2. Ensure the canister is securely installed on the therapy unit. If the canister is properly installed, the canister cannot be removed by gently pulling the canister directly away from the unit.

3. While therapy is on, apply gentle pressure and move your hand and fingers slowly around the edges of the drape and SensaT.R.A.C.™ Pad. The bar graph will lower and the frequency of the audible tone (if Seal Audio is on) will decrease when the leak is found.

4. Refer to the ***Application Instructions*** provided with V.A.C.® Dressings for information on using excess V.A.C.® Drape material to seal the leak area.

5. When finished press Exit to return to the *Clinician Home Screen*.

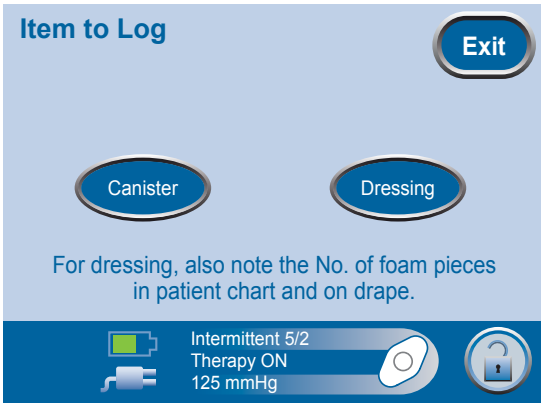
Log Tool Overview

The Log tool can be used to track:

- the number of foam pieces used during a dressing change.
- canister changes.

Logged information is viewable and exportable on the *Therapy History* screens.

How to Use Log Tool (When Starting Therapy)



From the *Clinician Home Screen* press Therapy On/Off then Log to access the *Item to Log* screen.

Press to log the time and date of a canister replacement.

Press to log the number of foam pieces used in a dressing change.

Press to return to the *Clinician Home Screen*.

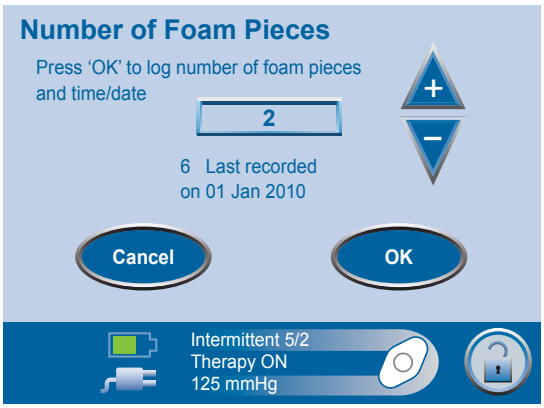
Canister Replaced Screen

From the *Clinician Home Screen* press Therapy On/Off then Log, then Canister to access the *Canister Replaced* screen.

Press to log that the canister has been replaced and return to the *Item to Log* screen. The current time and date will be recorded.

Press to return to the *Item to Log* screen without logging an entry.

Number of Foam Pieces Screen



From the *Clinician Home Screen* press Therapy On/Off then Log, then Dressing to access the *Number of Foam Pieces* screen.

Information displayed represents the last logged entry.

Use the + and - buttons to select the number of pieces of foam used during the current dressing change.

Press to log the number of foam pieces used and return to the *Item to Log* screen. The current time and date will be recorded.

Press to return to the *Item to Log* screen without logging an entry.

Always document the number of foam pieces used in patient chart and on the V.A.C.® Drape.

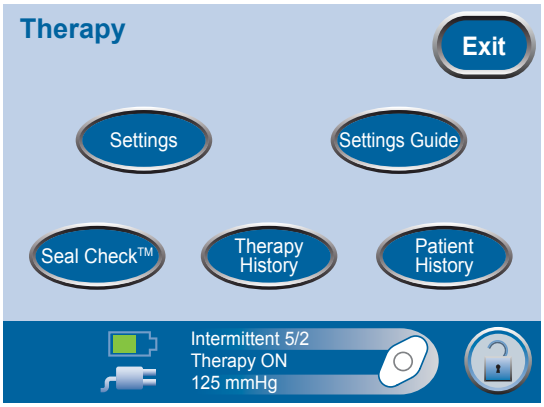
Logged information will appear in *Therapy History* as follows:

dd/mmm/yy	Time	Event
11/Jan/10	15:54	Canister Changed
11/Jan/10	15:55	Dressing Changed, 4

The numeral after "Dressing Changed" is the number of foam pieces recorded on the above screen.

Therapy Screen

The Therapy screen enables clinicians to change settings, select wound type, check the seal and view the therapy or patient hisstory.



From the *Clinician Home Screen* press Therapy to access the *Therapy* screen.

Press to manually set therapy.

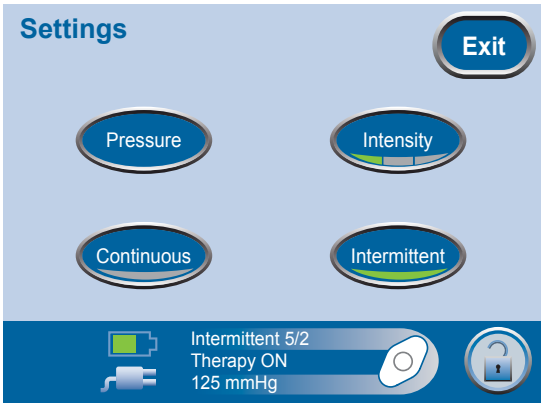
Press to access the settings guide for preset therapy settings.

Press for assistance in finding leaks.

Press to view or export therapy history.

Press to view or export patient history from the *Enter Access Code* screen.

Settings Screen (Manual)



From the *Clinician Home Screen* press Therapy, then OK, then Settings to access the *Settings* screen.

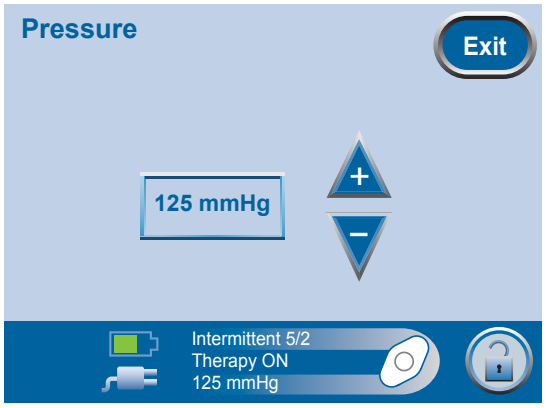
Press to change pressure settings.

Press to change intensity.

Press to toggle between *Continuous* and *Intermittent* therapy.

Press to set *Intermittent* therapy times.

Pressure Screen



From the *Clinician Home Screen* press Therapy, then OK, then Settings then Pressure to access the *Pressure* screen.

Use the + and - buttons to change the desired pressure.

Pressure can be set from 25 to 200 mmHg in increments of 25 mmHg. Press Exit to go to the *Confirm* screen.

Default setting is: 125 mmHg

Intensity Control

From the *Clinician Home Screen* press Therapy, then OK, then Settings to access the Intensity button.

- Intensity is related to the time it takes to reach the target therapy level after the initiation of therapy.
- The lower the intensity setting, the longer it will take for the target therapy level to be reached.
- KCI recommends that new patients begin therapy at the lowest intensity setting as this allows for slower increase of negative pressure once the foam is compressed in the wound.
- The intensity can remain at the minimum setting throughout the entire length of treatment, if desired.

Press to change levels. Green crescent changes with each setting.

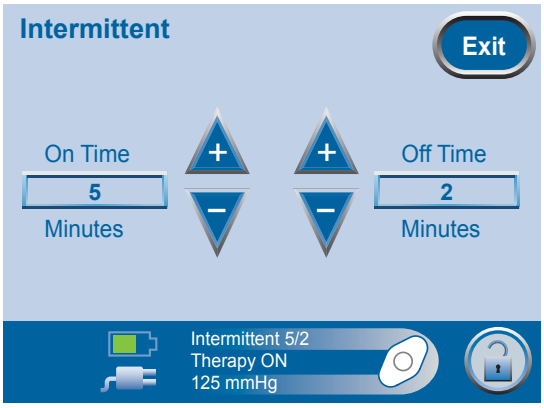
Low

Medium

High

Default setting is: Low.

Intermittent Screen



From the *Clinician Home Screen* press Therapy, then OK, then Settings, then Intermittent to access the *Intermittent* screen.

Use the + and - buttons to change the desired On and Off Time (in minutes).

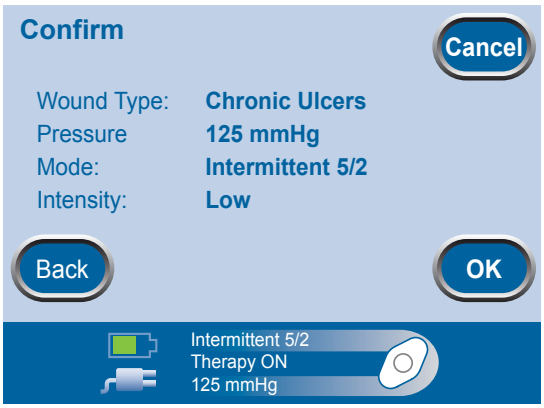
Both On and Off Times can be set from 1 minute to 10 minutes in 1 minute increments.

Exit — Press Exit to go to the *Confirm* screen.

Changing Intermittent time intervals will take effect in the next cycle.

Default setting is: On Time = 5 minutes, Off Time = 2 minutes.

Settings Confirmation



Exit — Press Exit when finished with the *Settings* screen to continue to the *Confirm* screen.

If the displayed settings are as desired, press OK to continue to the *Clinician Home Screen*. Otherwise, press Back to change any incorrect settings.

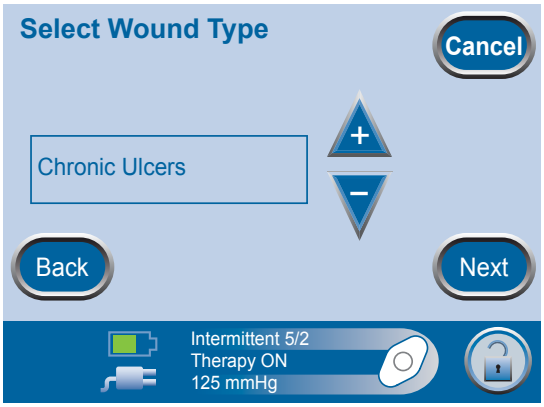
If settings were changed with V.A.C. Therapy off, press the Therapy On/Off button on the *Clinician Home Screen* to start therapy.

Settings Guide

The Settings Guide helps the clinician select from pre-set therapy ranges according to wound type and treating physician's orders. Selected ranges are a guide based on common settings for different wound types. Individual patient conditions may vary. Consult physician to verify settings for each patient.

Should physician orders fall outside the pre-set therapy ranges, select *Other* in this mode or use Manual Therapy Settings detailed on pages 22-24 in this manual.

Select Wound Type Screen

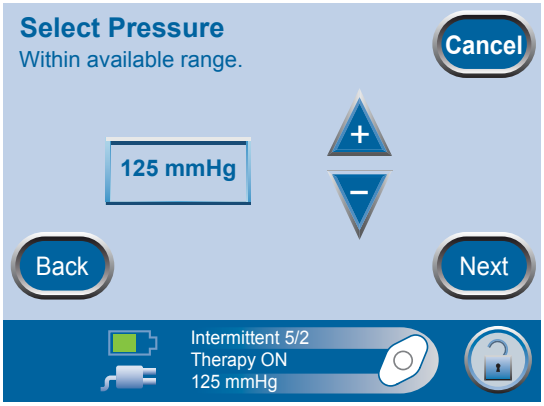


From the *Clinician Home Screen* press Therapy, then OK, then Settings Guide, then OK to access the *Select Wound Type* screen.

Use the + and - buttons to scroll through the available wound type selections.

Press Cancel on any screen to cancel and exit the procedure.

Select Pressure Screen

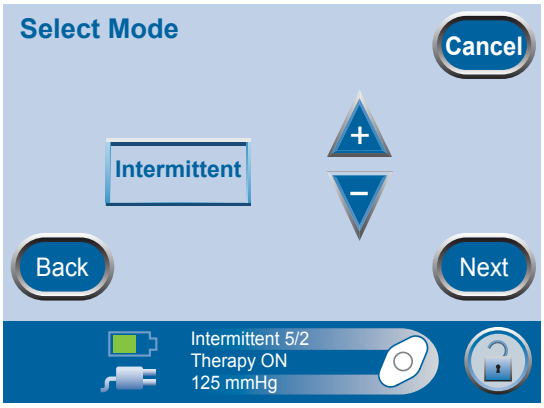


When finished with the *Select Wound Type* screen, press Next to continue to the *Select Pressure* screen.

Use the + and - buttons to scroll through the pressure selections.

Pressure selections are in ranges for the wound type selected on the previous screen.

Select Mode Screen



When finished with the *Select Pressure* screen, press Next and move to the *Select Mode* screen.

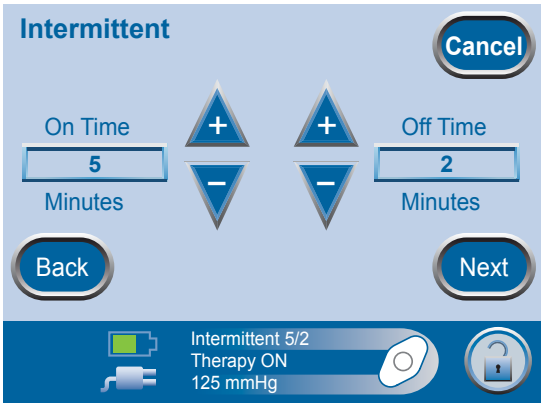
Use the + and - buttons to choose *Continuous* or *Intermittent* Therapy.

When finished with this screen, press Next.

If *Intermittent* is not an option for the wound type selected, the mode will not change.

***Intermittent* can be manually set from the *Settings* screen, or press Back and select *Other* as the wound type.**

Intermittent Type Screen



If Intermittent Therapy was chosen on the previous screen, this screen will appear.

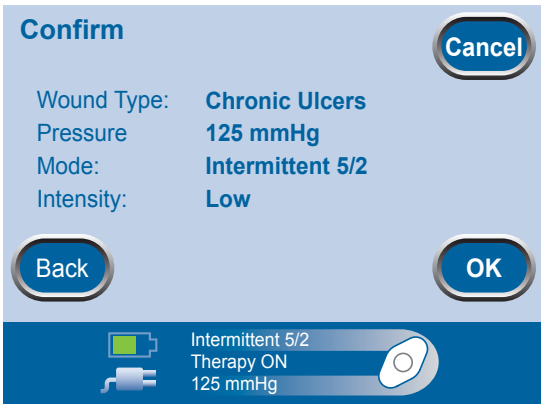
Use the + and - buttons to change the desired On and Off Time (in minutes).

Both On and Off Times can be set from 1 minute to 10 minutes in 1 minute increments.

When finished with this screen, press Next.

Default is: On Time = 5 minutes, Off Time = 2 minutes.

Settings Guide Confirmation



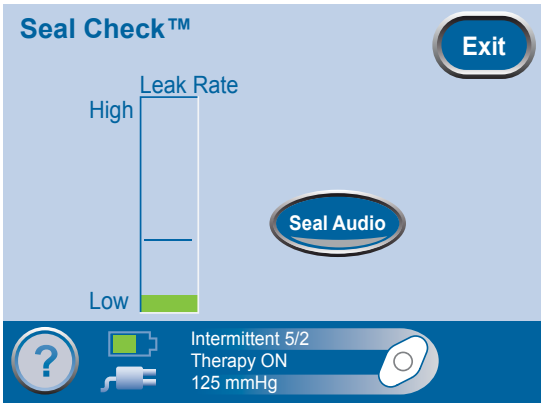
Once the settings are chosen, the Confirm screen will appear.

If the displayed settings are as desired, press OK to continue to the *Therapy* Screen. Otherwise, press Back to change any incorrect settings.

Settings take effect when OK is pressed.

Settings Guide Intensity default is *Low*. Intensity can only be changed using the Manual Therapy Settings (see pages 22-24).

Seal Check™ Screen



The *Seal Check™* screen provides a visual and audible representation of the air flow rate in the SensaT.R.A.C.™ system. For more information about Seal Check™ see pages 18-19.

From the *Clinician Home Screen* press Therapy, then OK, then Seal Check™ to access the *Seal Check™* screen.

Press Seal Audio to turn the Seal Audio tone on or off.

This tool can be used as an aid to ensure that the dressing system is correctly sealed.

Therapy History Screen

Therapy History
Exit
Date Time Event
18 Dec 2009 07:41:20 Low Intensity
18 Dec 2009 07:41:20 125 mmHg, Intermittent 5
18 Dec 2009 07:41:20 Therapy ON (Clinician M
18 Dec 2009 07:20:00 Therapy Inactive (Clinici
18 Dec 2009 07:04:59 Unit On (Clinician Mode)
17 Dec 2009 17:51:51 Unit Off (Clinician Mode)
Intermittent 5/2
Therapy ON
125 mmHg

The *Therapy History* screen displays the therapy information in date, time and event columns. The date is in ascending order and time is displayed using the twenty-four hour clock format.

From the *Clinician Home Screen* press Therapy, then OK, then Therapy History to access the *Therapy History* screen.

Use the + and - buttons to scroll to additional listings.

If wound history is recorded, see *Patient History* screen for wound progress history.

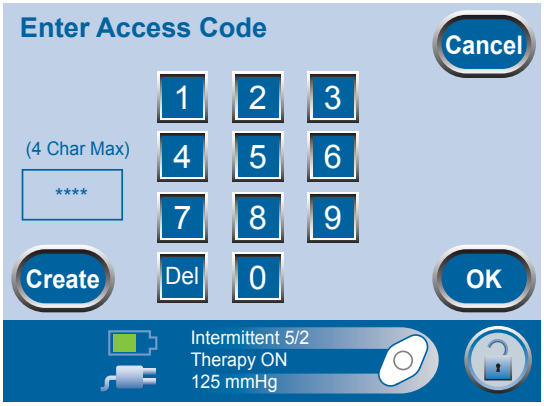
Press to return to the *Therapy* screen.

Patient History Screens

The Patient History screens enable a clinician to:

- Create a new access code.
- Delete the current patient record.
- Start a new patient record.
- View the patient record.
- Export history.
- View a wound image area graph.
- Analyze wound images.

Enter Access Code Screen



From the *Clinician Home Screen* press Therapy, then OK, then Patient History to access the *Enter Access Code* screen.

Press to proceed to the next screen.

Press to create a new access code.

Press to return to the *Therapy* screen.

This icon appears in the Therapy Status Bar and Display Area when a Patient Record is active.

For security purposes:

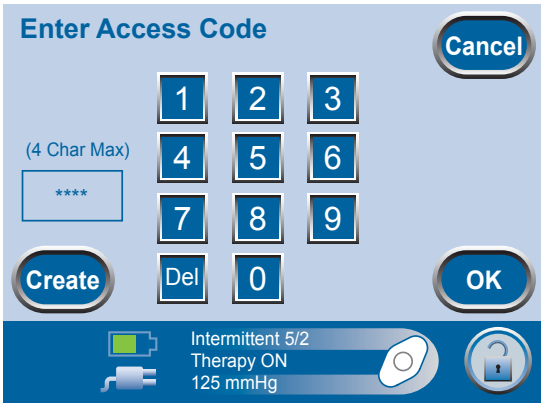
- **The InfoV.A.C.® Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.**

  All information will be automatically deleted when the unit is returned to KCI.

- **If a current access code is incorrectly entered, access to the *Patient History* screen will be denied and you will automatically be returned to the *Therapy* screen.**

- **If an incorrect access code is entered 10 times, the system will lock. Contact your local KCI representative.**

Enter Access Code Screen (cont.)



To create a new access code:

1. Press Create.

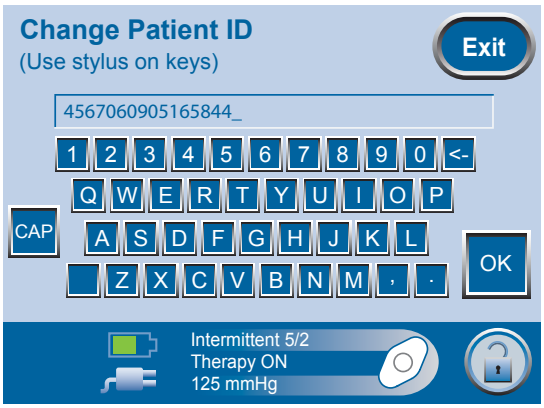
2. Enter your four digit numerical access code using the numbers on the screen, then press OK.

3. Re-enter your four digit numerical access code.

4. Press OK to set the new access code and proceed to the *Change Patient ID* screen.

Change Patient ID Screen

A unique number is automatically generated from the date and time unless a custom ID is created.


Change Patient ID
(Use stylus on keys)
Exit
4567060905165844_
1 2 3 4 5 6 7 8 9 0 <-
Q W E R T Y U I O P
CAP
A S D F G H J K L
OK
Z X C V B N M , .
Intermittent 5/2
Therapy ON
125 mmHg

1. Enter the new Patient ID on keyboard if desired.

2. Press OK when you have entered the new Patient ID, or are ready to proceed to the *Patient History* screen.

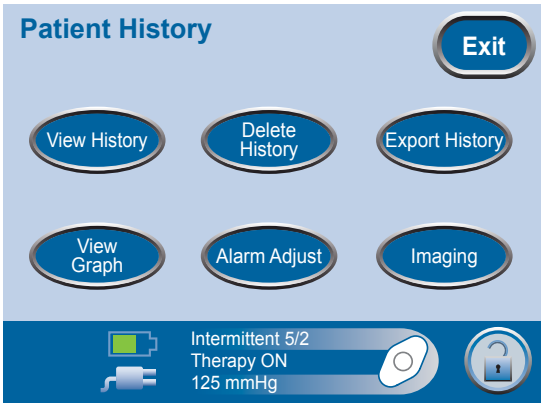
3. Press Exit to continue to the *Confirm* screen.

Press this button as a space bar.

Press this button to backspace/delete.

If no changes are made, the automatically generated number will be used as the Patient ID.

Patient History Screen



From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK to access the *Patient History* screen.

Press to view Patient History and add notes (up to 30 characters).

Press to delete a Patient History file.

Press to export Patient History and Therapy History.

Press to view a graphical representation of measured wound area over time.

Press to adjust Leak Alarm settings.

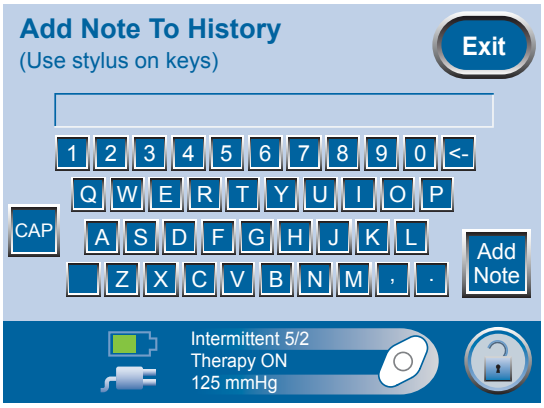
Press to view and perform Wound Image Analysis.

View History Screen

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then View History to access the *Patient History* screen.

The *Patient History* screen will display short notes (up to 30 characters) added by the clinician and/or medical staff. For a new Patient History this screen will be blank.

Add Note To History Screen


Add Note To History
(Use stylus on keys)
Exit
1 2 3 4 5 6 7 8 9 0 <-
Q W E R T Y U I O P
CAP
A S D F G H J K L
Z X C V B N M , .
Add Note
Intermittent 5/2
Therapy ON
125 mmHg

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then View History then Add Note on the *Patient History* screen to open the *Add Note to History* screen.

Use the screen keys to enter a note (up to 30 characters).

The notes entered will be displayed in the window area above the keys.

Press to log new note and return to *Patient History* screen.

Press this button as a space bar.

Press this button to backspace/delete.

Press to return to the *Patient History* screen.

Delete History Screen

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then Delete History to access the *Delete History* screen.

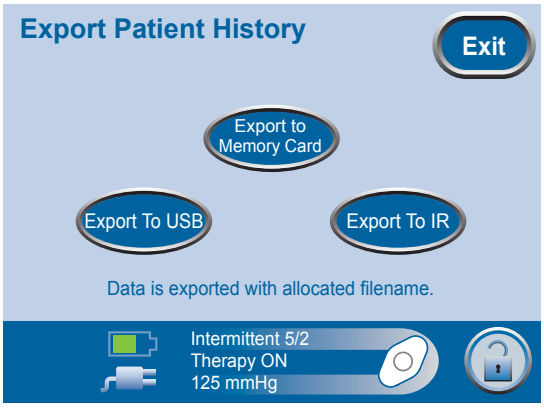
Deleted History cannot be recovered.

Press and hold Delete for two seconds to delete the Patient History Records. After the Patient History Records have been deleted, the screen will return to the *Therapy* screen.

Press to return to the *Patient History* screen without deleting Patient History.

All information will be automatically deleted when the unit is returned to KCI.

Export Patient History Screen



USB Data Port

Infrared Data Port

Memory Card Slot

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then Export History to access the *Export Patient History* screen.

The exported Patient History includes folders containing Therapy History, Patient History and all wound images for the current patient.

Image files are exported with the file names created during the imaging process.

Files can be exported to a Memory Card, Infrared or USB device.

Access the *Memory Card Transfer* screen.

Access the *USB Transfer* screen.

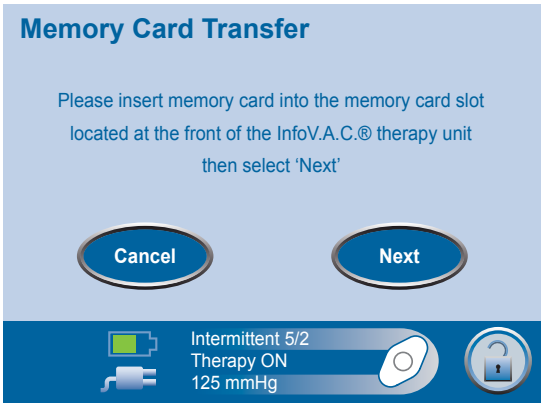
Access the *IR Transfer* screen.

The connection ports are for clinician use only.

Memory Card Transfer Screen

The Memory Card Slot is for authorized clinician access only.

1. Insert the Memory Card into the InfoV.A.C.® Therapy Unit Memory Card Slot. An audible *click* signals that the card is properly inserted.


Memory Card Transfer
Please insert memory card into the memory card slot located at the front of the InfoV.A.C.® therapy unit then select 'Next'
Cancel
Next
Intermittent 5/2
Therapy ON
125 mmHg

Export to Memory Card

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then Export History, then *Export to Memory Card* to access the *Memory Card Transfer* screen.

Next

2. Press Next to continue.

A progress bar on the screen will indicates transfer status.

OK

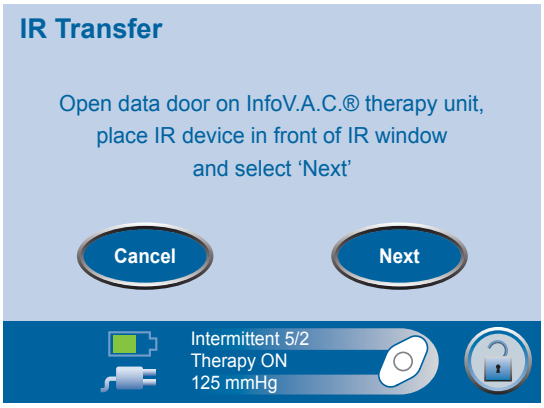
3. When the transfer is complete press OK to continue.

If the *Memory Card Transfer Error* screen appears when the Memory Card is inserted into the Memory Card Slot, files could not be transferred.

Possible reasons for transfer error:

- Card not inserted correctly.
- Incorrect format card.
- No images in the system.

IR Transfer Screen


IR Transfer
Open data door on InfoV.A.C.® therapy unit, place IR device in front of IR window and select 'Next'
Cancel
Next
Intermittent 5/2
Therapy ON
125 mmHg

The Infrared Data Port is for authorized clinician access only.

Export To IR

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then Export History, then *Export to IR* to access the *IR Transfer* screen.

1. Open the Data Door and position the IR device in front of the InfoV.A.C.® Therapy Unit.

2. Aim the IR Data Port of the transfer device at the Infrared Data Port on the InfoV.A.C.® Therapy Unit.

Next

3. Press Next to continue.

The InfoV.A.C.® Therapy Unit will attempt to establish a connection with the transfer device; once the connection is established, the transfer will begin.

A progress bar on the screen will indicates transfer status.

OK

4. When the transfer is complete press OK to continue.

If the *IR Transfer Error* screen appears, the InfoV.A.C.® Therapy Unit does not detect the IR device or the device is incompatible. Files could not be transferred.

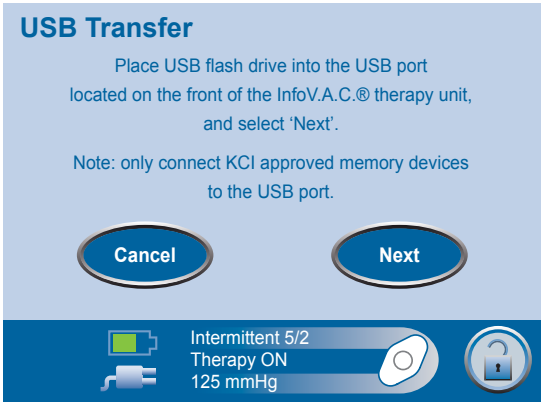
Possible reasons for transfer error:

- The IR transfer device is not lined up with InfoV.A.C.® Infrared Data Port.
- The IR transfer device's IR port is not active or is not set to receiving mode.
- Lenses on the IR device are damaged or obscured.

USB Transfer Screen

The USB port is for authorized clinician access only. USB devices should be connected directly and only unpowered USB mass storage devices should be attached to the InfoV.A.C.® Therapy Unit. AC or battery powered drives, computers, computer equipment, other devices or USB extension leads should not be connected to this device.

1. Insert the USB device into the InfoV.A.C.® Therapy Unit USB port.


USB Transfer
Place USB flash drive into the USB port located on the front of the InfoV.A.C.® therapy unit, and select 'Next'.
Note: only connect KCI approved memory devices to the USB port.
Cancel
Next
Intermittent 5/2
Therapy ON
125 mmHg

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then Export History, then *Export to USB* to access the *USB Transfer* screen.

2. Press Next to continue.

A progress bar on the screen will indicates transfer status.

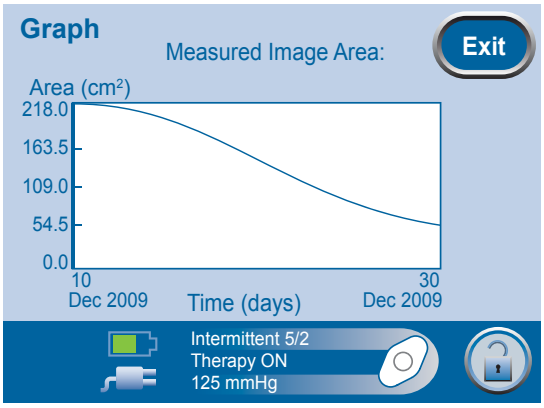
3. When the transfer is complete press OK to continue.

If the *USB Transfer Error* screen appears when the USB device is inserted into the USB port, files could not be transferred.

Possible reasons for transfer error:

- The USB device is not inserted correctly.
- The incorrect type of device is connected.

Graph Screen



View Graph

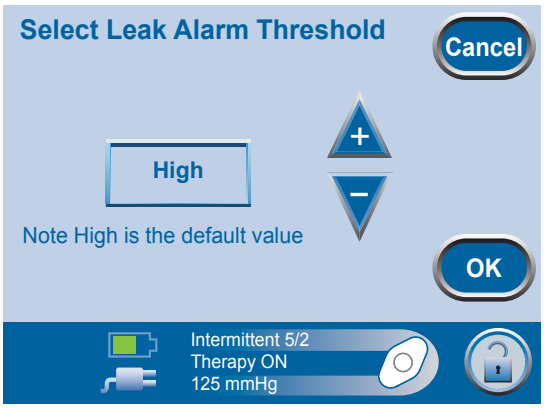
From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then View Graph to access the *Graph* screen.

The graph displays a representation of image area over time.

A graph cannot be constructed if the Patient History file has been deleted.

A graph cannot be constructed unless measurements of the image area have been previously saved in the patient's history log. At least two measurements from different days are required (area of the image against time) for a graph to be constructed.

Select Leak Alarm Threshold Screen



Consult the clinician prescribing therapy before making changes to this setting.

Alarm Adjust

From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then Alarm Adjust to access the *Select Leak Alarm Threshold* screen.

Use the + and - buttons to select the level of alarm adjustment required.

The InfoV.A.C.® Leak Alarm Threshold is set by default to High (2 Liters per minute), this screen allows a change to Low (1 Liter per minute) when appropriate.

OK

Press to confirm the alarm adjustment settings.

Wound Image Analysis

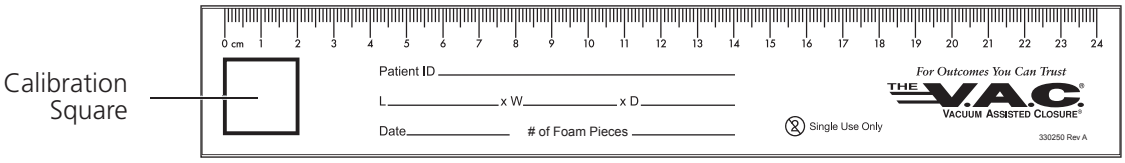
The Wound Imaging feature is an aid in recording treatment progress.

Wound imaging area and volume calculation features are not intended to be exact measurements and are not intended for use in the diagnosis and treatment of wounds.

Accessories required to utilize this feature include:

- Digital camera that uses an SD/MMC card. The maximum size of the SD/MMC card that can be used to upload images to an InfoV.A.C.® Therapy unit is 2 GB. The unit will not upload images using a SD/MMC card larger than 2 GB. Please check the size of the SD/MMC card prior to uploading images into the InfoV.A.C.® Therapy unit.

  The maximum picture resolution accepted by the InfoV.A.C.® Therapy unit is 2.2 megapixels. If using a camera with higher resolution, you must adjust the picture resolution settings on your camera to a setting of 2.2 megapixels or less. Please refer to your camera user manual for further instructions.
- An SD/MMC card.
- Calibration Reference Square. This is found on the ruler in the V.A.C.® Dressing package. This reference square is needed for the InfoV.A.C.® Therapy Unit to calculate wound measurements.


Calibration Square
0 cm 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
Patient ID
L x W x D
Date # of Foam Pieces
Single Use Only
For Outcomes You Can Trust
THE V.A.C.
VACUUM ASSISTED CLOSURE®
330250 Rev A

- Stylus. This is found inside the data door (see page 3). This is needed for tracing.

For optimal operation of the Wound Image Analysis feature it is recommended that:

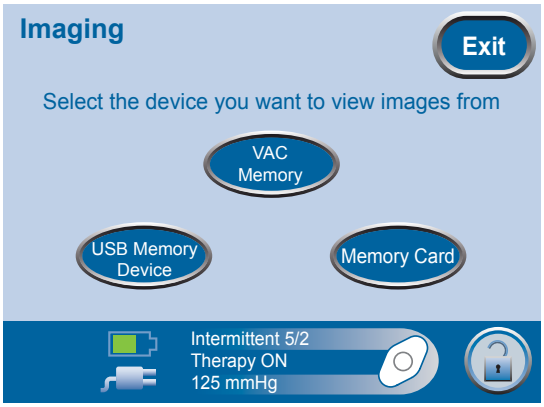
- The sterile Calibration Reference Square should be placed in the same location on the wound each time an image is taken.
- All images be taken from directly above the wound.
- The wound and Calibration Reference Square should fill as much of the image as possible.
- The image should be taken in good light conditions.
- Images must be taken directly from the camera, not transferred or downloaded to the card from a computer.

Using a camera that has a date and time function will allow for easier tracking of images.

Troubleshooting Suggestions:

- **Media Image Capacity:** Keep as few images on the media as possible prior to uploading the images into the InfoV.A.C.® Therapy unit. It is recommended you upload any existing pictures from your media (SD/MMC card or USB memory stick) to your computer prior to capturing new wound photos on the media. By having too many images on the media, you run the risk of receiving a "DSP Not Initialized" error which will freeze the unit, preventing image upload.
- **"DSP Not Initialized" Error:** This indicates an issue with the image uploading and prevents the unit from uploading images into the InfoV.A.C.® Therapy unit. If you receive this error, exit to the previous screen and reset the unit by turning the unit off and back on again. If you cannot go back to the previous screen, reset the unit by turning the unit off and back on again. You may then proceed to the image uploading screen as directed in this manual on page 40.
- **Screen Freezes during Image Uploading:** This indicates an issue with the image uploading into the InfoV.A.C.® Therapy unit. If you receive this error, reset the unit by turning the unit off and back on again. You may then proceed to the image uploading screen as directed in this manual on page 40.
- **Erasing Images from the Unit:** Digital images cannot be individually erased from the InfoVAC.® Therapy unit. When the internal memory is full and more pictures need to be uploaded, the patient history must be cleared by deleting the record and creating a new patient history. It is recommended that the patient history record be exported prior to deleting so all history and images are saved. See pages 29-37 of this manual for further instructions on viewing, deleting, exporting, and creating a patient history record.

Imaging Screen



From the *Clinician Home Screen* press Therapy, then OK, then Patient History, then enter or create an access code and press OK, then Imaging to access the *Imaging* screen.

Press to select and view an image from the SD/MMC card.

Press to select and view an image from a USB device.

Press to select and view an image from the InfoV.A.C.® Therapy Unit internal memory.

There will be a short delay while the images are accessed from the internal memory or the memory card. The relevant button will be highlighted with a green rim to indicate that this is in progress.

When the InfoV.A.C.® Therapy Unit is ready, the *File Select* screen will appear.

If V.A.C.® Memory is selected for a new Patient Record, no images will be available and the image thumbnail will be black.

File Select Screen

The number of files available for viewing and the number of the currently-viewed file (for example, 9 of 10) is displayed in the upper right of the *File Select* screen.

1. Use the + and - buttons to select the next or the previous image.

2. Press Select when the required image is displayed.

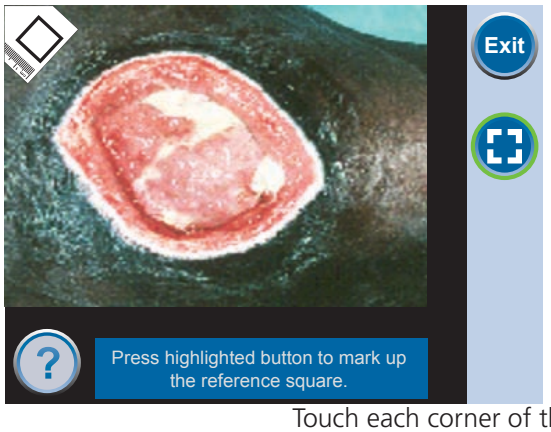
Images being opened from a memory card or USB device will be automatically downloaded into the InfoV.A.C.® Therapy Unit internal memory.

Press to begin the Wound Area Trace procedure.

Press to calculate the wound area inside the highlighted trace outline.

Press to begin the Wound Volume calculation procedure.

Image Reference Calibration



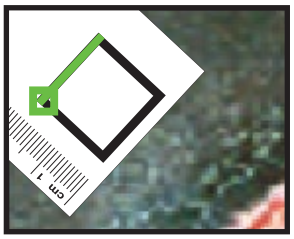
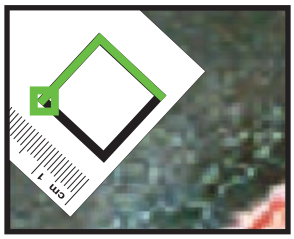
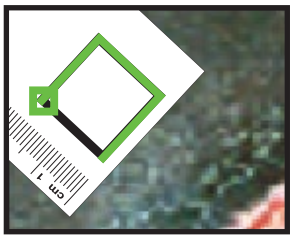
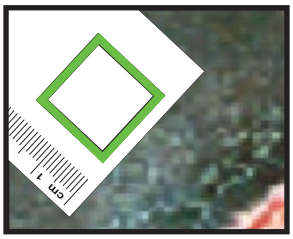
Trace the reference square in the image to scale the image area and volume measurements.

On-screen instructions are provided at the bottom of each screen to guide the user through the process

Use only the stylus provided to trace the reference square.

Press to begin the Calibration Reference process.

Touch each corner of the reference square. When the last corner of the reference square is touched the corner points will be joined by a highlighted line.

1. 
2. 
3. 
4. 

It is important to select corners in either a clockwise or counter-clockwise manner. Incorrect sequence will lead to a calibration error.

If necessary, press to restart the Calibration Reference process.

Wound Area Trace

Next, trace the outline of the wound area. Press the button pictured at left to begin the Wound Area Trace procedure. The *Select Image Area* screen will appear.

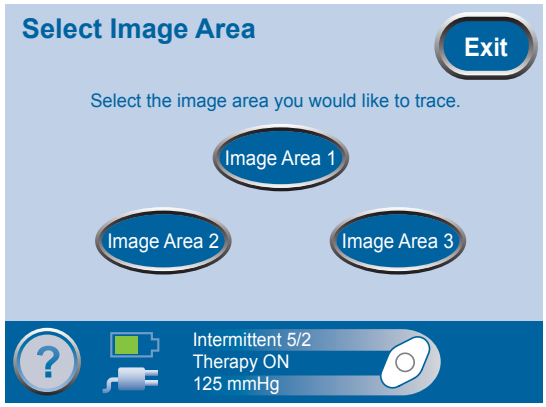


Image Area 1

Press Image Area 1 to trace the overall outline of the wound area. All traces and results for Image Area 1 will be displayed in yellow.

The InfoV.A.C.® Therapy Unit only stores the area and depth of Image Area 1 in the Patient Log. This information in the Patient Log is used to construct a graph.

Image Area 2

Press Image Area 2 to trace another area inside the wound. All traces and results for Image Area 2 will be displayed in blue.

Image Area 3

Press Image Area 3 to trace an additional area. All traces and results for Image Area 3 will be displayed in pink.

Once an Image Area is selected, the image will be displayed as a full screen.

Draw around the required area with the stylus.

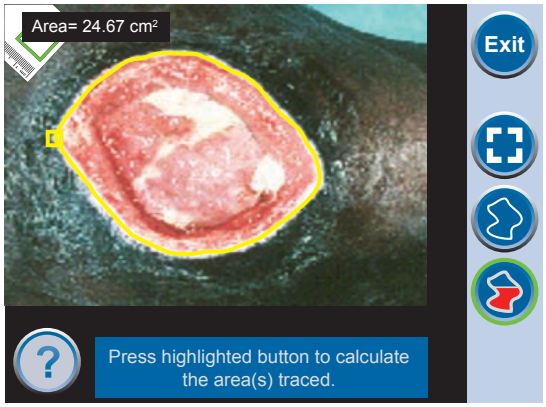
- A yellow square will appear at the start point. The trace is completed when the end of the yellow line returns to the start point.

To correct an error, tap the stylus in the square at the start point. This action will return you to the previous screen where you can select to retrace the area.

When the outline of the wound image area is complete, the buttons will reappear.

If required, press to trace additional areas.

Calculate Wound Area

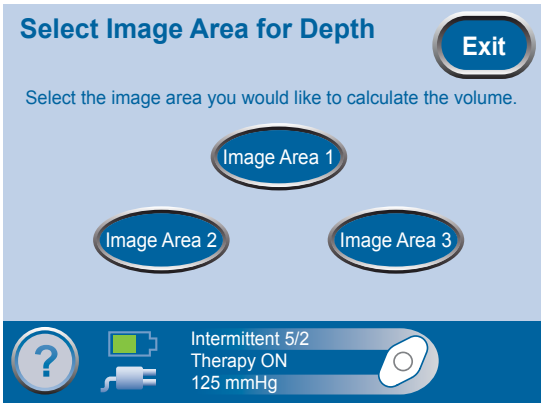


Press to calculate the wound area inside the highlighted trace outline.

The results will be displayed in the color of the trace for the appropriate measured area.

Calculate Wound Volume

Select Image Area for Depth Screen



The wound volume can be calculated from the areas previously traced and the measured depth.

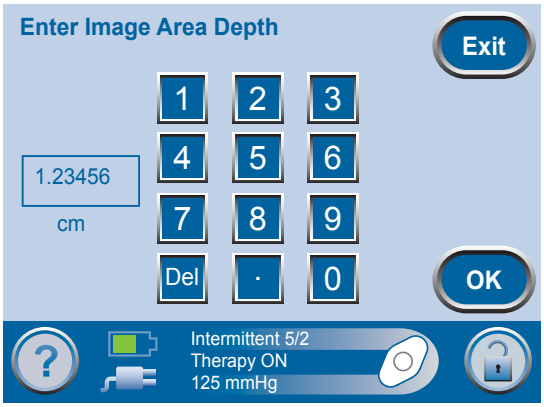
Press to begin the Wound Volume calculation procedure. The *Select Image Area for Depth* screen will appear.

Image Area 1 — Press to enter the depth of Image Area 1.

The InfoV.A.C.® Therapy Unit only stores the area and depth of Image Area 1 in the Patient Log. This information in the Patient Log is used to construct a graph.

Image Area 2 — Press to enter the depth of Image Area 2.

Image Area 3 — Press to enter the depth of Image Area 3.



Use the screen keys to enter the image depth.

OK — Press OK when finished entering image depth.

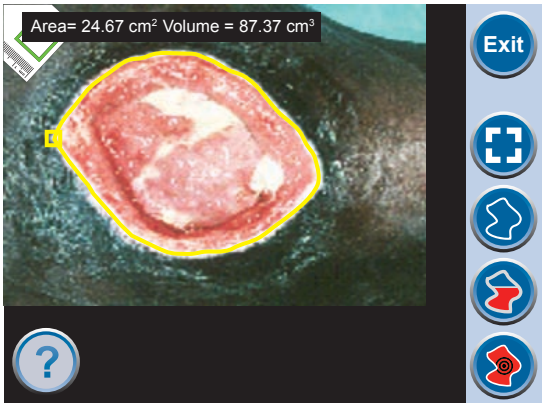
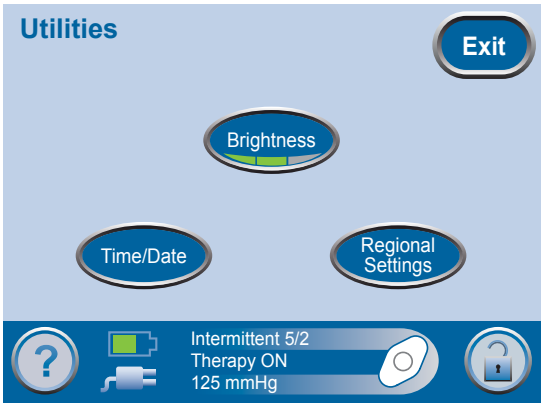


Image area and volume will be displayed on the screen at left.

Exit — Press Exit to return to the *Patient History* screen.

Clinician Utilities



From the *Clinician Home Screen*, press Utilities to access the *Utilities* screen.

From this *Utilities* screen the clinician can:

- Set the time and date to current time and calendar date.
- Adjust regional settings.
- Set the brightness of the touch screen user interface. The green crescent at the bottom of the button indicates the level of brightness:

Low

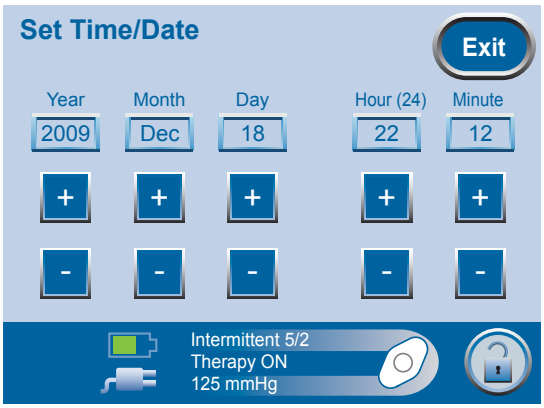
Medium

High

The Default setting is Medium

Press to return to the *Clinician Home Screen*.

Changing Time and Date

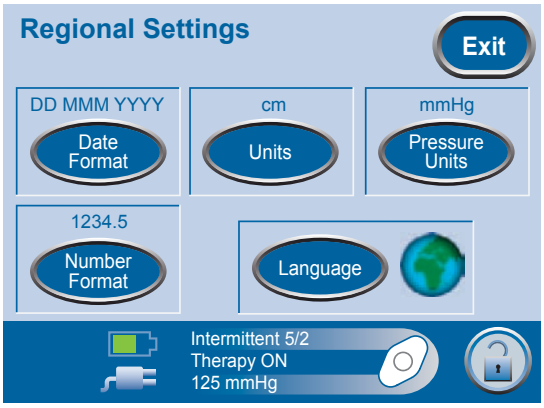


From the *Clinician Home Screen* press Utilities, then press Time/Date to access the *Set Time/Date* screen.

Press to set current local time and calendar date. Holding these buttons will rapidly scroll through available selections.

Press to return to the *Utilities* screen.

Changing Pressure Units and Date Format



Regional Settings

From the *Clinician Home Screen* press Utilities, then press Regional Settings to access this screen.

Pressure Units

Press to switch between mmHg (millimeters of mercury) and kPa (kilo-pascals) units of measurement.

The InfoV.A.C.® Therapy Unit is designed to show two units of measure with mmHg (millimeters of mercury) being the default. If you prefer kPa (kilo-Pascals), press Pressure Units to switch from mmHg to kPa.

Number Format

Press to change how decimals are displayed.

Units

Press to select cm (centimeters) or in (inches)

Language

Press to change the language in which the screens are displayed.

Date Format

Press to switch between displaying DD/MMM/YYYY (Day-Month-Year) and MMM/DD/YYYY (Month-Day-Year) formats.

Default settings are: mmHg, DD/MMM/YYYY, cm and English.

Exit

Press Exit to return to the *Utilities* screen.

ATTENTION: Important Information about Alerts and Alarms

An ***Alert*** will be displayed on the touch screen user interface when the InfoV.A.C.® Therapy Unit detects a condition that requires patient or caregiver attention.

Alerts will be accompanied by a ***single*** audible tone.

An ***Alarm*** will be displayed on the touch screen user interface when the InfoV.A.C.® Therapy Unit detects a condition that ***requires immediate patient or caregiver attention in order to ensure the prescribed therapy is being delivered.***

Alarms will be accompanied by a ***repeating*** audible tone.

If alarm conditions cannot be resolved, contact your caregiver or local KCI representative.

Press Audio Pause to silence the audible tone for 2 minutes.

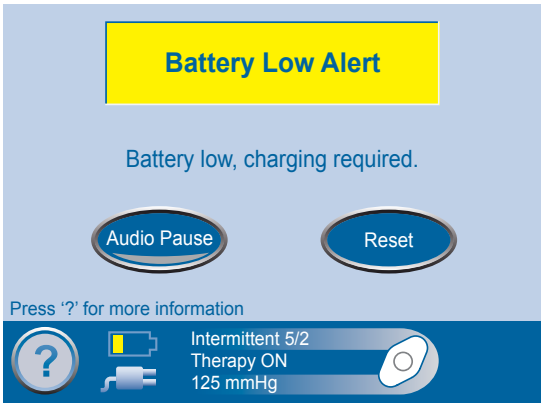
Press Help for more information about the alert or alarm.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

This applies to all alarm conditions when therapy is interrupted.

Battery Low Alert

The *Battery Low Alert* screen indicates approximately two hours of battery power remain. This alert will be accompanied by a *single* audible tone.



This alarm may be silenced during troubleshooting by pressing Audio Pause.To resolve this alert:

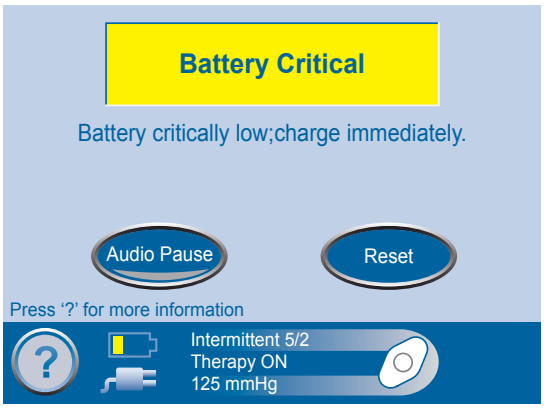
1. Connect therapy unit to wall outlet using InfoV.A.C.® power supply to recharge battery. An amber light above the power connection will indicate unit is charging. Refer to the ***Charging the Battery*** section of this manual (page 4) for more information.

2. Press Reset on this screen to return to the *Home Screen*.

V.A.C.® Therapy continues.

Battery Critical Alarm

The *Battery Critical* alarm screen indicates approximately 30 minutes of battery power remain. This alarm will be accompanied by a *repeating* audible tone.



This alarm may be silenced during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Connect therapy unit to wall outlet using InfoV.A.C.® power supply to recharge battery. An amber light above the power connection will indicate unit is charging. Refer to the ***Charging the Battery*** section of this manual (page 4) for more information.

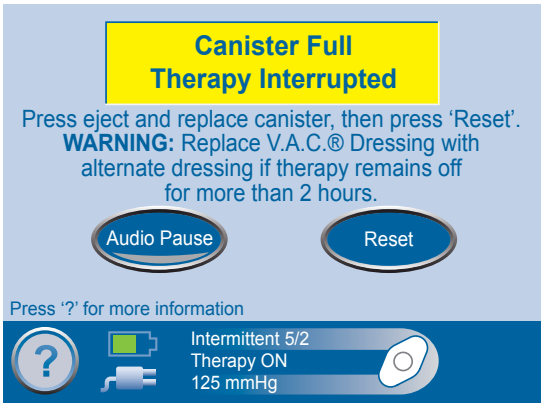
2. Press Reset on this screen to return to the *Home Screen*.

3. Ensure therapy is on by confirming that the green crescent is lit on the Therapy On/Off button. If not, press the Therapy On/Off button to restart therapy.

V.A.C.® Therapy continues; however, if this alarm is not resolved within one minute, therapy will be interrupted.

Canister Full Therapy Interrupted Alarm

The *Canister Full Therapy Interrupted* alarm screen appears when the InfoV.A.C.® Therapy Unit detects that the canister is full and should be replaced. This alarm will be accompanied by a *repeating* audible tone.


Canister Full
Therapy Interrupted
Press eject and replace canister, then press 'Reset'.
WARNING: Replace V.A.C.® Dressing with alternate dressing if therapy remains off for more than 2 hours.
Audio Pause
Reset
Press '?' for more information
Intermittent 5/2
Therapy ON
125 mmHg

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

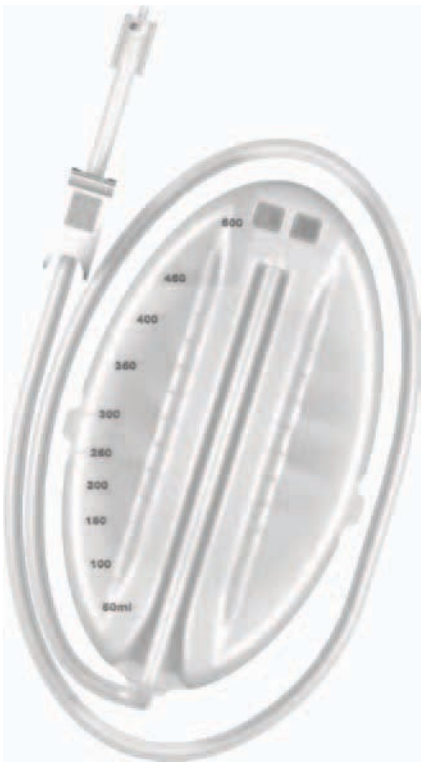
1. Determine if canister is full by comparing the level of fluid to the graduated marks on the canister (see below).

2. If canister is not full, press Reset.

3. If canister is full, change canister and press Reset to return to the *Home Screen*.

See the *Changing the Canister* section of this manual (page 9) for additional information.

4. Restart therapy by pressing Therapy On/Off on the *Home Screen*.



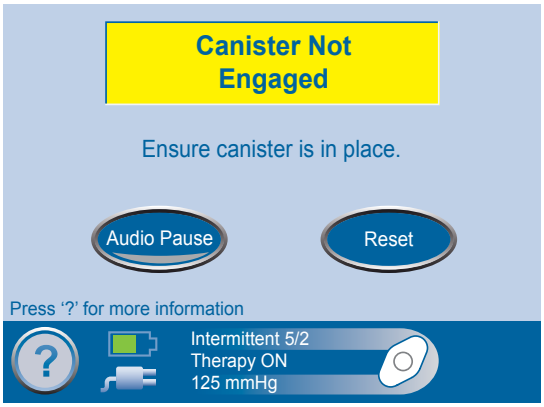
500 mL canister

1000 mL canister

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is off for more than two hours.

Canister Not Engaged Alarm

The *Canister Not Engaged* alarm screen appears when the InfoV.A.C.® Therapy Unit detects that the canister is not fully seated and properly latched. This alarm will be accompanied by a *repeating* audible tone.



Audio Pause

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Remove the canister by pressing the Canister Release button.

2. Inspect the canister and InfoV.A.C.® Therapy Unit to ensure that foreign objects or debris do not interfere with the canister and therapy unit mating surfaces.

3. Ensure both seals are present. If seals are missing or damaged, contact your local KCI representative.

4. Re-attach the canister to the InfoV.A.C.® Therapy Unit ensuring that the canister is fully engaged and latched. An audible click indicates that the canister is properly installed.

Reset

5. Press Reset on this screen to return to the *Home Screen*.

On/Off

6. Restart therapy by pressing Therapy On/Off.

If this alarm continues to appear, repeat steps 1 through 6 with a new canister. If alarm condition cannot be resolved, contact your healthcare professional or local KCI representative.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Leak Alarm

The *Leak Alarm* screen appears when the InfoV.A.C.® Therapy Unit detects a significant negative pressure leak. If this alarm is not resolved in three minutes, therapy will be interrupted. This alarm will be accompanied by a *repeating* audible tone.

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Ensure connector between dressing tubing and canister tubing is properly locked.

2. Ensure canister is fully engaged. (See ***Canister Not Engaged Alarm*** [page 49].)

3. Press Seal Check™ to use the Seal Check™ tool to help identify leaks in dressing.

Refer to the *Finding a Leak Using Seal Check™* section of this manual (page 19) for details on how to use Seal Check™.

The patient's only access to the Seal Check™ tool is through this *Leak Alarm* screen.

4. Refer to the ***Dressing Application Instructions for Use*** provided with V.A.C.® Dressings for information on using excess V.A.C.® Drape material to seal the leak area.

5. Once the leak has been resolved, press Reset on this screen to return to the *Home Screen*.

6. Ensure therapy is on by confirming that the green crescent is lit on the Therapy On/Off button. If not, press the Therapy On/Off button to restart therapy.

If this alarm is not resolved within three minutes, the Leak Alarm Therapy Interrupted alarm will appear and therapy will stop.

Refer to *Leak Alarm Therapy Interrupted* section (page 51) for procedures to restart therapy.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Leak Alarm Therapy Interrupted

The *Leak Alarm Therapy Interrupted* screen appears when the InfoV.A.C.® Therapy Unit has detected a leak that has not been resolved and therapy has been interrupted. This alarm will be accompanied by a *repeating* audible tone.

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Press Reset on this screen to return to the *Home Screen*.

2. Restart therapy by pressing Therapy On/Off.

If the leak condition is not resolved, access the Seal Check™ tool for further troubleshooting:

From the *Clinician Mode Screen*, Therapy On/Off opens the *Seal Check™* screen on the *Therapy Start* screen.

or

From the *Clinician Home Screen* press Therapy, then OK, then Seal Check™ to access the *Seal Check™* screen.

The patient's only access to the Seal Check™ tool is only through the *Leak Alarm* screen.

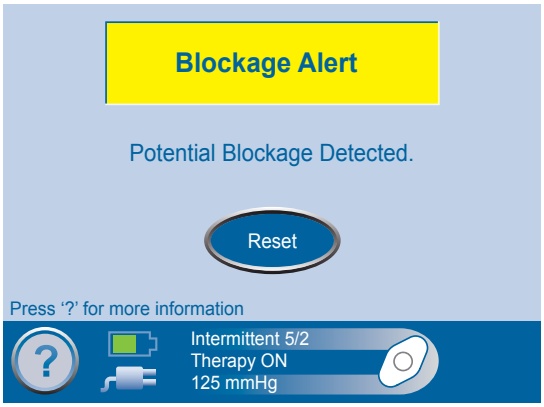
Should the leak not be resolved within three minutes, the alarm screen will once again appear and therapy will stop.

If alarm condition cannot be resolved, contact your healthcare professional or local KCI representative.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Blockage Alert

The *Blockage Alert* screen appears when the InfoV.A.C.® Therapy Unit has detected a potential blockage. This alert will be accompanied by a *single* audible tone.



To resolve this alert:

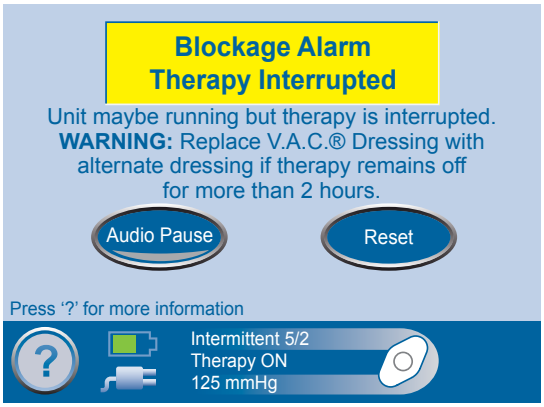
1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Blockage Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.

4. Press Reset on this screen to return to the *Home Screen*.

The InfoV.A.C.® Therapy Unit continues to attempt to apply therapy.

Blockage Alarm Therapy Interrupted

The *Blockage Alarm Therapy Interrupted* screen appears when the InfoV.A.C.® Therapy Unit has determined that a blockage is present. This alarm will be accompanied by a *repeating* audible tone.



This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Blockage Alarm Therapy Interrupted remains after completing steps 1 and 2, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.

4. Press Reset on this screen to return to the *Home Screen*.

WARNING: Therapy unit remains on; however, negative pressure at the wound is below therapeutic value.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

If alarm condition cannot be resolved, contact your local KCI representative..

Low Pressure Alert

The *Low Pressure Alert* screen appears when the InfoV.A.C.® Therapy Unit has not reached the selected therapy set pressure. This alert will be accompanied by a *single* audible tone.

To resolve this alert:

1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Low Pressure Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.
4. Press Reset to return to the *Home Screen*.

V.A.C. Therapy is still being applied, but at a lower than selected pressure.

Low Pressure Alarm Therapy Interrupted

The *Low Pressure Alarm Therapy Interrupted* screen appears when the InfoV.A.C.® Therapy Unit has not reached the selected therapy set pressure and negative pressure at the wound is below therapeutic value. This alarm will be accompanied by a *repeating* audible tone.

Low Pressure Alarm Therapy Interrupted
WARNING: Unit may be running, but therapy is interrupted. Press '?' for more information
Audio Pause
Reset
Intermittent 5/2
Therapy ON
125 mmHg

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Low Pressure Alarm Therapy Interrupted remains after completing steps 1 and 2, lowering the therapy unit and tubing to be level with or below the wound site may resolve this alarm. If the alert is cleared by lowering the unit, normal use may resume.

4. Press Reset on this screen to return to the *Home Screen*

WARNING: Therapy unit remains on; however, negative pressure at the wound may be below set pressure, potentially compromising therapeutic benefits.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

If alarm condition cannot be resolved, contact your local KCI representative.

Therapy Inactive Alarm

The *Therapy Inactive* alarm screen appears when the InfoV.A.C.® Therapy Unit has detected that V.A.C.® Therapy has been off for fifteen minutes (with the unit powered on) without the touch screen user interface being touched. This alarm will be accompanied by a *repeating* audible tone.

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

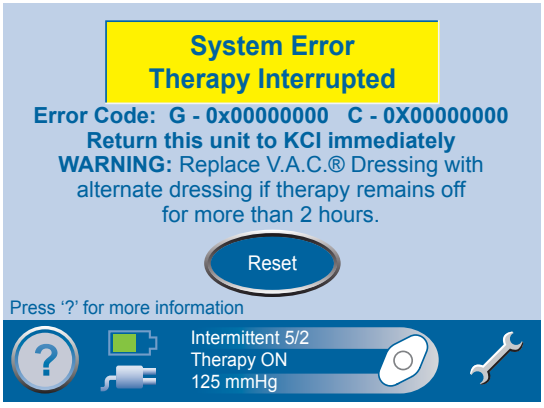
1. Press Reset on this screen to return to the *Home Screen*.

2. Restart therapy by pressing Therapy On/Off.

3. If V.A.C.® Therapy is not desired, turn the InfoV.A.C.® Therapy Unit off by using the Power On/Off button on the front of the unit.

System Error Alarm Therapy Interrupted

The *System Error Therapy Interrupted* alarm screen appears when there is a technical fault within the InfoV.A.C.® Therapy Unit. Several different types of system errors may occur. A number will appear in the yellow alarm box that represents the diagnostic code of the technical fault. This alarm will be accompanied by a *repeating* audible tone.


System Error
Therapy Interrupted
Error Code: G - 0x00000000 C - 0X00000000
Return this unit to KCI immediately
WARNING: Replace V.A.C.® Dressing with alternate dressing if therapy remains off for more than 2 hours.
Reset
Press '?' for more information
Intermittent 5/2
Therapy ON
125 mmHg

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Record the error number.

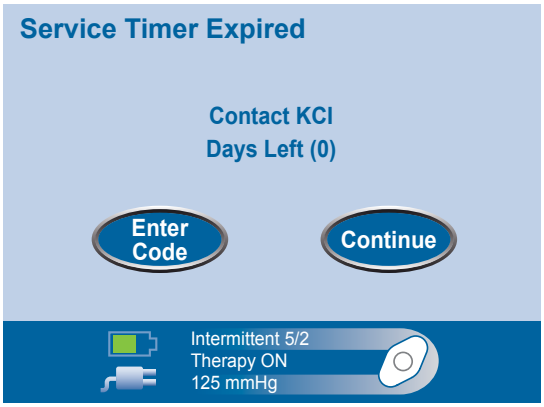
2. Power the unit off and then on using the Power On/Off button on the front of the unit.

3. If error persists, contact your healthcare professional or local KCI representative.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Service Timer Expired Alert

The *Service Timer Expired* alert screen appears when the InfoV.A.C.® Therapy Unit has reached its service time limit. Once the Service Timer has expired, this alert will appear every time the unit is powered up. When Days Left reaches zero, this alert will reappear periodically during therapy.



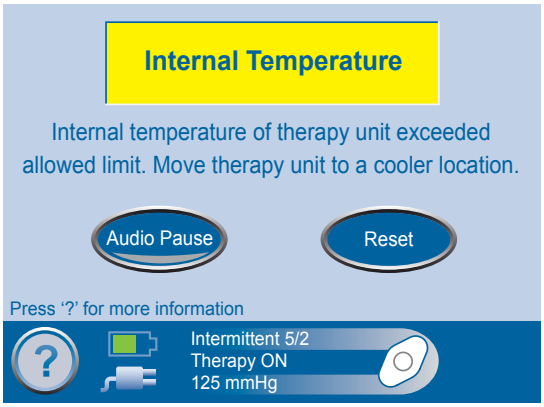
To resolve this alert:

1. Contact your local KCI representative to obtain a new service timer code.

2. Press Enter Code to enter the code obtained from KCI.

Internal Temperature Alarm

The *Internal Temperature* alarm screen appears when the internal temperature of the InfoV.A.C.® Therapy Unit has reached its maximum limit. Therapy continues while this alarm is active. The screen will be turned off after five minutes, but will illuminate when touched. Battery charging is stopped. This alarm will be accompanied by a *repeating* audible tone.



To resolve this alarm:

1. Move the InfoV.A.C.® Therapy Unit to a cooler location.

2. If error persists, contact your local KCI representative.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Pressure Deviation Therapy Interrupted

The *Pressure Deviation Therapy Interrupted* alarm screen appears when the wound pressure has deviated above the system limits. This alarm will be accompanied by a *repeating* audible tone.

Pressure Deviation Therapy Interrupted
The wound pressure has deviated above system limits. Therapy has been stopped.
Contact KCI
Audio Pause
WARNING Press '?' for more information
Intermittent 5/2
Therapy ON
125 mmHg

This alarm may be silenced for two minutes during troubleshooting by pressing Audio Pause.

To resolve this alarm:

1. Power the unit off and then on using the Power On/Off button on the front of the unit.
2. If error persists, contact your local KCI representative.

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Standard Precautions

The following are the KCI recommended daily and weekly cleaning and infection control procedures for the InfoV.A.C.® Therapy Unit.

Always follow Standard Precautions.

Standard Precautions are designed to reduce the risk of transmission of microorganisms from both known and unknown sources of infection. These precautions can be applied to all patients, regardless of their diagnosis or presumed infection status, and should be used when contact is anticipated with blood and all body fluids. This also includes secretions and excretions (except sweat) regardless of whether blood is visible or not, non-intact skin (i.e., open wounds) and mucous membranes.

Waste Disposal

Discard all disposable items (all tubing, connectors, clamps, used canister, used dressings, etc.) in accordance with local medical waste disposal regulations.

Cleaning the InfoV.A.C.® Therapy Unit

Cleaning and disinfection of the InfoV.A.C.® Therapy Unit includes wipedown of all hard surface components. Follow your institutional procedures used for cleaning and disinfection of other hard surface durable electronic medical equipment. The InfoV.A.C.® Therapy Unit must be cleaned and disinfected:

- If it becomes soiled during patient use.
- At least weekly.
- In between patients.

Ensure that the InfoV.A.C.® Therapy Unit and its power supply are not connected to AC power when using cleaning fluids of any nature.

- KCI recommends the following regarding cleaning and disinfecting KCI V.A.C.® Therapy devices:
- To help reduce risk of infection and contact with blood and body fluids, use personal protective equipment (PPE) such as medical procedure gloves.
- Clean all organic material (visible soil or body secretions) from the therapy unit prior to disinfection.
- Use hospital-grade cleaners and disinfectants.
- Do not immerse or saturate the therapy unit with fluids to avoid damage to the electronics in the device.
- Do not use alcohol based solutions around the touchscreen edges or near gasket and power switches since alcohol based solutions will easily wick up into the screen and may cause equipment malfunction.

Cleaning the Touch Screen

1. Select the Screen Guard button on the *Home* screen (pg. 14) to activate Screen Guard.

Lock button icon will close. The next screen displayed will be the Screen Guard screen.

2. Use a soft, non-abrasive cloth to gently clean the Touch Screen.

Do not use any liquid to clean the Touch screen.

Do not use excessive force to clean the Touch Screen. Pressing too hard may damage the Touch Screen.

3. To unlock the Touch Screen, select the 1 button, then the 2 button on the *Screen Guard* screen to return to the *Home* screen.

Specifications

Technical Specifications

Classification.....Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

InfoV.A.C.® Therapy Unit

Continuous Operation
Type B Equipment
Class II or Internally Powered Equipment
Ordinary Equipment

Dimensions: InfoV.A.C.® Therapy Unit

Dimensions..... 23cm X 22cm X 17.5cm (9.05in X 8.6in X 6.8in)
Weight 2.89kg (6.37lbs)

Power Supply

Class I Equipment
Ordinary Equipment

Electrical Data (Power Supply)

Voltage ..... 100 - 240 VAC
Frequency ..... 50Hz - 60Hz
Power 60W

Storage and Environmental conditions

Storage Temperature Range..... -10 °C to +50 °C (14°F to 122°F)
Operational Temperature Range..... +10 °C to +30 °C (50°F to 86°F)
Relative Humidity Range..... 10% to 85% non-condensing
Barometric Pressure Range ..... 700 hPa to 1060 hPa

The KCI InfoV.A.C.® Therapy Unit conforms to the following International Standards:
BS EN 60601-1:1990, BS EN 60601-1-1:2001, BS EN 60601-1-2:2001, BS EN 60601-1-4:1996, BS EN 60601-1-8:2004, UL 60601-1 1st edition, CAN CSA-C22.2 No. 601.1-M90, ISO 11137:1995, ISO 11737-1:1995, ISO 11737-2:1998, ISO 11607:2003, ISO 10993-1:2003, ISO 10993-4:2002, ISO 10993-5:1999, ISO 10993-10:2002, USP 26.

Explanation of Symbols Used

Warning or Caution statement of possible hazard to system, patient or staff.

Important operational information

Caution: Consult Accompanying Documents

Warning of possible trip hazard

Power the device on or off. This button will light up when the device is on.

Release the canister. This button will flash when the canister is full and needs to be replaced.

This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.

Conforms to the Medical Devices Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive.

Authorized Representative in the European Community

Manufacturer

Serial Number

Not Protected against Harmful Effects of Water

Direct Current

Type B Applied Part

Class II Device

Conforms to UL Std 60601-1 Certified to CAN/CSA C22.2 No. 601.1-M90

Customer Contact Information

For questions regarding this product, supplies, maintenance, or additional information about KCI products and services, please contact KCI or a KCI authorized representative, or:

In the US call 1-800-275-4524 or visit www.kci1.com.

Outside the US visit www.kci-medical.com.

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